

REC'D 26 MAY 2000

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 03283-99 Z/ks	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/US99/09875	International filing date (day/month/year) 06/05/1999	Priority date (day/month/year) 06/05/1998
International Patent Classification (IPC) or national classification and IPC A61N7/00		
Applicant EXOGEN, INC. et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.



2. This REPORT consists of a total of 5 sheets, including this cover sheet.

- ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☐ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 03/12/1999	Date of completion of this report 24.05.2000
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Stern, M Telephone No. +49 89 2399 2239 

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/US99/09875

I. Basis of the report

1. This report has been drawn on the basis of (*substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments.*):

Description, pages:

1-19 as originally filed

Claims, No.:

1-87 as originally filed

Drawings, sheets:

1/5-5/5 as originally filed

2. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
☐ the claims, Nos.:
☐ the drawings, sheets:

3. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

4. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application.
☒ claims Nos. 1-87.

because:

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/US99/09875

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (*specify*):

☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 1-81 are so unclear that no meaningful opinion could be formed (*specify*):

see separate sheet

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for the said claims Nos. 82-87.

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/US99/09875

1. For the following reasons, claims 1-81 lack clarity in the sense of Article 6 PCT.
 - 1.1 It is clear from the description on page 3, lines 3-9 and from the sentence bridging pages 8 and 9 of the description that the bandages of the invention should have an adhesive layer which serves both purposes, (a) to **adhere** the transducer material(s) to the backing layer, and (b) **to adhere the bandage onto the patient**.

However, the definitions of the bandages according to independent claims 1 and 41 entirely omit to specify the second mentioned purpose, and vaguely refer to the first one (by defining the transducer material(s) to be merely "disposed" on the adhesive layer; in this respect see point 1.3 below). Hence, claims 1-81 do not meet the requirement following from Article 6 PCT taken in combination with Rule 6.3(b) PCT insofar as the independent claims must contain all the technical features essential to the definition of the invention.

- 1.2 This is all the more so, since the aforementioned purposes are presented in the description as a means to differentiate the present invention from the cited prior-art document **US-A-4 787 888** (cited on page 2, line 16 to page 3, line 2, and hereinafter referred to as **D1**). Note in Fig. 3 of D1, that the piezoelectric polymers 51 and 55 in Fig. 3 of D1 are adhered to the backing layer 50 by an implicit adhesive layer, which is "substantially coextensive" with the surface of the backing layer.
 - 1.3 It should be noted that by specifying the "adhesion" of the transducer material(s) on the adhesive layer - instead of vaguely defining the transducer material(s) as being "disposed on" said layer -, the bandages of claims 1 and 41 would be non-obviously distinguished over document **EP-A-0 679 371** (cited in the search report, hereinafter referred to as **D2**). In fact, note that the adhesive layer on the lower surface of layer 14 in Fig. 2 of D2 is on the opposite surface on which the transducer materials 16 and 15 are disposed (see in D2, column 3, lines 43-58 and column 4, lines 10-20), so that the transducer material(s) are "disposed on" the layer 14.
 - 1.4 For consistency with the aforementioned essential aspects of the present

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invention, the methods of manufacturing the bandages of the invention defined in independent method claims 22 and 62 should have been amended accordingly.

2. The mentioned lack of clarity precludes at present any meaningful assessment of novelty and inventive step.
3. Had the mentioned essential aspects of the invention been incorporated into the independent claims 1, 22, 41 and 62, as required by Article 6 PCT, they would have also satisfied the requirements of novelty and inventive step.

The reasons are the following. The feature of the transducer being adhered to the same layer which serves to adhere the bandage onto the patient, clearly allows a greater ease of manufacture compared to the manufacturing process necessary for the bandages of D1 and D2. In these, in fact, a separate adhesive layer for attaching the transducer to the backing layer and adhering the bandage to the patient has to be provided.

4. Reference signs in parentheses should have been inserted in the claims to increase their intelligibility, Rule 6.2(b) PCT.

E.K.

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 601-53 PCT	FOR FURTHER ACTION see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.	
International application No. PCT/US 99/ 09875	International filing date (day/month/year) 06/05/1999	(Earliest) Priority Date (day/month/year) 06/05/1998
Applicant EXOGEN, INC. et al.		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 5 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

- a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

- b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing :

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. ☒ **Certain claims were found unsearchable** (See Box I).

3. ☐ **Unity of invention is lacking** (see Box II).

4. With regard to the **title**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

☐ the text is approved as submitted by the applicant.

☒ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No.

☐ as suggested by the applicant.

☒ because the applicant failed to suggest a figure.

☐ because this figure better characterizes the invention.

1

☐ None of the figures.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 99/ 09875

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 82-87
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

Box III TEXT OF THE ABSTRACT (Continuation of item 5 of the first sheet)

The abstract is changed as follows:

line 1: after "bandages" insert "(10)",
line 2: after "bandages" insert "(10)",
line 4: after "layer" insert "(13)",
line 5: after "layer" insert "(14)", and after "backing layer" insert "(13)",
line 6: after "material" insert "(16)", and after "layer" insert "(14)",
line 7: after "backing layer" insert "(13)", after "adhesive layer" insert "(14)",
line 8: after "backing layer" insert "(13)",
line 9: after "materials" insert "(16)",
line 11: after "layer" insert "(14)", after "bandages" insert "(10)",
line 14: after "bandages" insert "(10)"

INTERNATIONAL SEARCH REPORT

International Application No.

US 99/09875

A. CLASSIFICATION OF SUBJECT MATTER

IPC 6 A61N7/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61N G10K A61H A61M B06B A61F A61L

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 4 787 888 A (FOX MARTIN D) 29 November 1988 (1988-11-29) cited in the application	1-3, 22-24, 41-43, 62-64
A	column 3, line 63 - column 4, line 4; figure 1	6,20,27, 40,46, 60,66,81
Y	EP 0 181 506 A (EDO WESTERN CORP) 21 May 1986 (1986-05-21)	1-3, 22-24, 41-43, 62-64
A	page 6, line 7 - line 13; figure 1	6,20,27
A	page 7, line 3 - line 8	40,46, 60,81

☒ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search

28 July 1999

Date of mailing of the international search report

04/08/1999

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2

NL - 2280 HV Rijswijk

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Authorized officer

Mayer, E

INTERNATIONAL SEARCH REPORT

International Application No.

US 99/09875

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 4 933 230 A (CARD ROGER J ET AL) 12 June 1990 (1990-06-12)	4-9, 25-29
A	column 4, line 29 - line 43	44-49
A	column 5, line 44 - line 48 ---	65-70
A	EP 0 679 371 A (ORTHOSONICS LTD) 2 November 1995 (1995-11-02)	1, 11, 16, 21, 22
A	column 7, line 9 - line 26; figure 3	31, 36
A	column 8, line 28 - line 36 ---	41, 51, 56, 61, 62, 72, 77
A	EP 0 536 875 A (NDM ACQUISITION CORP) 14 April 1993 (1993-04-14)	3, 17, 18, 24, 37
A	column 4, line 30 - line 35; figure 2 -----	38, 43, 57, 58, 64, 78, 79

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

US 99/09875

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
US 4787888	A	29-11-1988	NONE	
EP 0181506	A	21-05-1986	AT 66543 T	15-09-1991
			CA 1264371 A	09-01-1990
			DE 3583850 A	26-09-1991
			JP 61172081 A	02-08-1986
			US 4733379 A	22-03-1988
US 4933230	A	12-06-1990	US 4726099 A	23-02-1988
EP 0679371	A	02-11-1995	AU 691253 B	14-05-1998
			AU 1762095 A	09-11-1995
			GB 2288741 A, B	01-11-1995
			JP 8098863 A	16-04-1996
			NZ 272009 A	24-02-1997
			US 5656015 A	12-08-1997
			ZA 9503345 A	11-01-1996
EP 0536875	A	14-04-1993	US 5160328 A	03-11-1992
			AU 641322 B	16-09-1993
			AU 1945792 A	11-02-1993
			CA 2073274 A	08-02-1993
			JP 1998476 C	08-12-1995
			JP 5184621 A	27-07-1993
			JP 7034812 B	19-04-1995
			NZ 243404 A	26-08-1994

PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

To:

Assistant Commissioner for Patents
United States Patent and Trademark
Office
Box PCT
Washington, D.C.20231
ÉTATS-UNIS D'AMÉRIQUE

in its capacity as elected Office

Date of mailing (day/month/year) 05 January 2000 (05.01.00)	
International application No. PCT/US99/09875	Applicant's or agent's file reference 601-53 PCT
International filing date (day/month/year) 06 May 1999 (06.05.99)	Priority date (day/month/year) 06 May 1998 (06.05.98)
Applicant TALISH, Roger, J. et al	

1. The designated Office is hereby notified of its election made:

☒ in the demand filed with the International Preliminary Examining Authority on:

03 December 1999 (03.12.99)

☐ in a notice effecting later election filed with the International Bureau on:

2. The election
- ☒
- was

☐ was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Authorized officer Diana Nissen
Facsimile No.: (41-22) 740.14.35	Telephone No.: (41-22) 338.83.38

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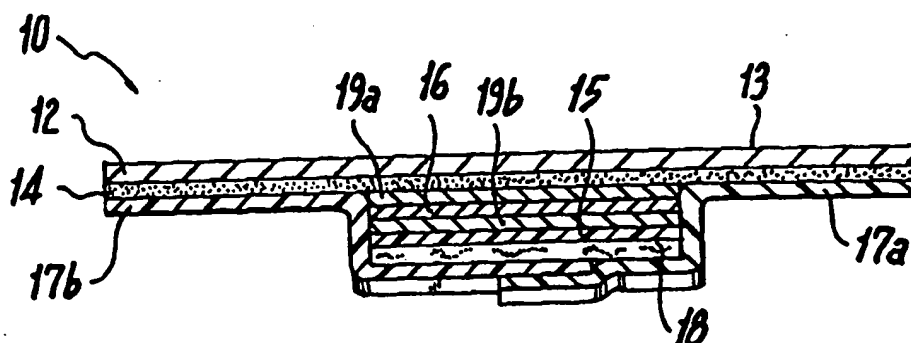
WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61N 7/00	A1	(11) International Publication Number: WO 99/56829 (43) International Publication Date: 11 November 1999 (11.11.99)
<p>(21) International Application Number: PCT/US99/09875</p> <p>(22) International Filing Date: 6 May 1999 (06.05.99)</p> <p>(30) Priority Data: 60/084,453 6 May 1998 (06.05.98) US</p> <p>(71) Applicant (for all designated States except US): EXOGEN, INC. [US/US]; 10 Constitution Avenue, Piscataway, NJ 08855 (US).</p> <p>(72) Inventors; and (75) Inventors/Applicants (for US only): TALISH, Roger, J. [US/US]; 5 Harman Court, Hillsborough, NJ 08876 (US). WINDER, Alan, A. [US/US]; 56 Patrick Road, Westport, CT 06880 (US).</p> <p>(74) Agents: CARTER, David, M. et al.; Dilworth & Barrese, 333 Earle Ovington Boulevard, Uniondale, NY 11553 (US).</p>	<p>(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).</p> <p>Published With international search report.</p>	

(54) Title: ULTRASOUND BANDAGES



(57) Abstract

Ultrasound bandages (10) and ultrasound transducer array bandages are provided herein to accelerate the healing of wounds by positioning the ultrasound bandages (10) and ultrasound transducer array bandages adjacent to a wound and generating ultrasonic pulses. The ultrasound bandages generally include (a) a backing layer (13), (b) an adhesive layer (14) applied to, and substantially coextensive with, the backing layer (13), and (c) a transducer material (16) disposed on at least a portion of the adhesive layer (14). The ultrasound transducer array bandages generally include (a) a backing layer (13), (b) an adhesive layer (14) applied to, and substantially coextensive with, the backing layer (13), and (c) an array comprising a plurality of transducer materials (16) arranged in adjacent relation to define spaces therebetween, the array being disposed on at least a portion of the adhesive layer (14). The resulting ultrasound bandages (10) and ultrasound transducer array bandages allows for medical therapeutic applications as promoting the healing of wounds such as abrasions, lacerations, incisions and ulcers at any section or multiple sections of the human anatomy with the ultrasound bandages (10) and ultrasound transducer array bandages being conveniently discarded after each application and a new bandage then being applied for the next application.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
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ULTRASOUND BANDAGES

BACKGROUND OF THE INVENTION

1. Field of the Invention

Novel ultrasound bandages and ultrasound transducer array bandages are described herein. Also described are methods for manufacturing the ultrasound
5 bandages and ultrasound transducer array bandages. Additionally, use of the ultrasound bandages and ultrasound transducer array bandages in medical therapeutic ultrasound applications, e.g., for promoting the healing of wounds, i.e., wound healing, such as abrasions, lacerations, incisions and venous ulcers, are also described herein.

10 2. Description of the Related Art

The therapeutic value of ultrasonic waves is known. For example, U.S. Patent No. 4,530,360 to Duarte describes a basic non-invasive therapeutic technique and apparatus for applying ultrasonic pulses externally on the skin of the patient at a location adjacent to a bone fracture site. The applicator described in the '360 patent has
15 a plastic tube which serves as a grip for the operator, an RF plug attached to the plastic tube for connection to an RF source, and internal cabling connected to a rigid ultrasonic transducer. To apply the ultrasonic pulses during treatment, an operator manually holds the applicator in place until the treatment is complete. The '360 patent also describes a range of RF signals for creating the ultrasound, ultrasound power density
20 levels, a range of duration for each ultrasonic pulse, and a range of ultrasonic pulse frequencies.

As another example, U.S. Patent Nos. 5,003,965 and 5,186,162, both to Talish and Lifshy, describe an ultrasonic body treatment system in which the RF generator and transducer are both part of a modular applicator unit which is placed at the skin location. Both the '965 and '162 patents are concerned with healing, for example, bone fractures by placing the body treatment system within a cast and then surrounding the treatment site with the cast.

Yet another example is U.S. Patent No. 5,211,160 to Talish and Lifshy which describes a bandage assembly which is mounted on uncovered body parts, i.e., without a cast or other medical wrapping. The bandage assembly is typically wrapped around the region of the body, e.g., the leg, being subjected to ultrasonic therapy with a treatment head unit containing an ultrasonic transducer being removably assembled to the bandage assembly during treatment.

While these prior art systems provide accelerative healing of soft tissue wounds and bone fractures, none of the systems provide an ultrasound bandage having an adhesive layer with a transducer material disposed thereon for treatment of wounds.

Previous attempts have been made to provide a bandage having a transducer material. For example, U.S. Patent No. 4,787,888 discloses a bandage assembly for percutaneous administration of a medicament. The bandage assembly described in the '888 patent has a bandage member with a cavity containing a medicament and having two transducer materials, e.g., piezoelectric polymers, extending thereacross with a pair of electrical contacts disposed adjacent the opposite surfaces of the transducer material. The transducer materials, however, are employed to produce sonic vibrations

in the material from a sonic generator to stretch the pores of the skin thereby inducing the medicament into the pores for therapeutic treatment.

It would be desirable to provide an ultrasound bandage having an adhesive layer with a transducer material disposed on at least a portion thereof such that the bandage can be applied to the portion of the skin at or near a wound by way of the adhesive layer and the transducer material facilitating the transfer of acoustic energy during each therapeutic application to promote the healing of the wound with the ultrasound bandage being discarded upon completion of each application.

10 SUMMARY OF THE INVENTION

Novel ultrasound bandages and ultrasound transducer array bandages for use in therapeutic applications have been discovered. In one embodiment, the novel ultrasound bandages include at least a backing layer, an adhesive layer applied to, and substantially coextensive with, the backing layer, and a transducer material disposed on at least a portion of the adhesive layer. Electrode surfaces can be applied to opposite surfaces of the transducer material with a matching layer being applied to, and substantially coextensive with, the electrode surface not applied to the adhesive layer. A coupling pad can then be applied to, and substantially coextensive with, the matching layer.

20 In another embodiment, an ultrasound transducer array bandage is formed by disposing on at least a portion of an adhesive layer which is applied to, and substantially coextensive with, a backing layer, an array comprised of a plurality of

transducer materials arranged in adjacent relation to define spaces therebetween.

Electrode surfaces can be applied to opposite surfaces of each transducer material with a matching layer being applied to, and substantially coextensive with, the electrode surface not applied to the adhesive layer. A coupling pad can then be applied to, and
5 substantially coextensive with, the array.

A method for making the ultrasound bandage has also been discovered. In the method, an adhesive layer is applied to, and substantially coextensive with, a backing layer, and a transducer material is disposed on at least a portion of the adhesive layer.

A method for making an ultrasound transducer array bandage has also been
10 discovered. In the method, an adhesive layer is applied to, and substantially coextensive with, a backing layer, a plurality of transducer materials are arranged in adjacent relation to define spaces therebetween to form an array, the array being disposed on at least a portion of the adhesive layer, and, optionally, a coupling pad is applied to, and substantially coextensive with, the array.

15 A method for using the ultrasound bandage or ultrasound transducer array bandage in therapeutic applications has also been discovered. In the method, the ultrasound bandage or ultrasound transducer array bandage can be applied to a wound on the human anatomy or, alternatively, adjacent to the wound, in need of therapeutic stimulation and that section of the human anatomy is then exposed to a dosage amount
20 of acoustic energy.

The term "wound" for the purposes of "wound healing" shall be understood herein to include ulcers such as venous ulcers, burns, ulcerated wounds due to, for

example, diabetes, incisions such as surgical incisions or other surgical cuttings including stitched surgical cuttings, skin grafts, hair transplants, revascularization, bed sores, tissue dehiscence, ligament and tendon repair and reconstruction, abrasions and lacerations.

5 The ultrasound bandages and ultrasound transducer array bandages described herein possess at least an adhesive layer having at least one transducer material disposed on at least a portion thereof to advantageously permit acoustic energy generated by the transducer(s) to be efficiently applied and coupled to the contours of the human anatomy for therapeutic applications. Additionally, after each application of
10 therapeutic treatment, the ultrasound bandages and ultrasound transducer array bandages can be conveniently discarded with a new bandage being applied to the human anatomy for the next therapeutic application.

BRIEF DESCRIPTION OF THE DRAWINGS

15 Preferred embodiments of the invention are described below with reference to the drawings, which are described as follows:

FIG. 1 is a schematic cross-sectional view of an ultrasound bandage in accordance with the present invention;

FIG. 2A is a schematic cross-sectional view of the ultrasound bandage of FIG. 1
20 with a thicker coupling material;

FIG. 2B is a schematic transverse cross-sectional view of the ultrasound bandage of FIG 2A taken along axis 2B-2B illustrating the coupling material configured

as a wedge;

FIG. 3 is a schematic top view of the ultrasound bandage of FIG. 1 in an assembly;

FIG. 4 schematic side view of the ultrasound bandage assembly of FIG. 3 in accordance with the present invention;

FIG. 5 schematic cross-sectional view of a ultrasound transducer array bandage in accordance with the present invention;

FIG. 6A is a schematic cross-sectional view of the ultrasound transducer array bandage of FIG. 5 with a thicker coupling material;

FIG. 6B is a schematic transverse cross-sectional view of the ultrasound transducer array bandage of FIG 6A taken along axis 6B-6B illustrating the coupling material configured as a wedge;

FIG. 7 is a schematic top view of the ultrasound transducer array bandage of FIG. 5 in an assembly;

FIG. 8 is a schematic top view of ultrasound bandage possessing indicia thereon;

FIG. 9 is a perspective view of the ultrasound bandage assembly of FIG. 3 in use in accordance with the present invention; and,

FIG. 10 is a perspective view of the ultrasound transducer array bandage of FIG. 5 in use in accordance with the present invention.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

One embodiment of an ultrasound bandage in accordance with the present invention is shown generally in FIG. 1 at 10. In general, the ultrasound bandage includes a backing layer 12 possessing upper and lower surfaces. Adhesive layer 14 is applied to, and substantially coextensive with, lower surface 13 of backing layer 12 for securing the ultrasound bandage 10 to the skin of the patient. Transducer material 16 can be disposed on at least a portion of adhesive layer 14 or, alternatively, transducer material 16 can be applied within at least a portion of adhesive layer 14. In this way, transducer material 16 can be removed, if desired, prior to disposal of ultrasound bandage 10 after use. Electrode surfaces 19a and 19b can be applied to, and substantially coextensive with, opposite surfaces of transducer material 16. Matching layer 15 can be applied to, and substantially coextensive with, electrode surface 19b. Coupling pad 18 can be applied to, and substantially coextensive with, matching layer 15, thereby providing an efficient coupling path between the transducer material 16 and the patient's skin and soft tissue for delivery of acoustic energy to the wound in need of therapeutic treatment. Alternatively, coupling pad 18 can include end portions (not shown) which extend beyond and fold over matching layer 15 to adhere to adhesive layer 14. Release liners 17a and 17b seal and protect adhesive layer 14, transducer material 16 and coupling pad 18 during the residency of ultrasound bandage 10 within its package with release liner 17a overlapping release liner 17b.

In general, backing layer 12 can be any material, woven or non-woven, synthetic or natural, porous or non-porous, perforated or non-perforated, elastic or non-

elastic, which will provide support and act as a protective covering for the bandage 10.

Suitable materials include, for example, cellophane, cellulose acetate, ethyl cellulose, plasticized vinyl acetate-vinyl chloride copolymers, ethylene-vinyl acetate copolymer, polyethylene terephthalate, nylon, polyethylene, polypropylene, polyvinylidene,

5 chloride, paper, cloth, aluminum foil and the like. Preferably, backing layer 12 is a moisture vapor permeable, liquid impermeable flexible thin film or sheet with the thin film being more preferred. A preferred thin film for use herein is a polyurethane film. If desired, the backing layer 12 can be fabricated from a composite of films. The composite can be a metallized, e.g., aluminized, film or a laminate of two or more
10 films or a combination thereof. For example, a laminate of polyethylene terephthalate and polyethylene or a polyethylene/metallized polyethylene terephthalate/polyethylene laminate can be employed. Useful polymers include polyethylene, polypropylene, polyvinyl chloride, polyethylene terephthalate and the like. The width and thickness of backing layer 12 will vary according to the size of the bandage employed and are
15 conventional in the art. Therefore, these widths and thicknesses need not be discussed in detail herein.

Adhesive layer 14 of bandage 10 is preferably a pressure sensitive adhesive layer and can be selected from any of the known and conventional medical grade adhesives, e.g., those based on polyacrylic, polyvinylether, or polyurethane resins.

20 Useful pressure sensitive adhesives include those disclosed in U.S. Patent No. 4,573,996, the contents of which are incorporated by reference herein. It is an essential requirement that the amount of adhesive layer 14 applied to lower surface 13

of backing layer 12 be sufficient to achieve an acceptable level of adhesion of ultrasound bandage 10 to the skin and to apply and adhere transducers 16. Thus, the various shapes and sizes of adhesive layer 14 will depend, for example, on the area of a patient's body to which they are applied, the size and weight of transducer material 16, the size and shape of the external wound, etc. The amount of adhesive that will satisfy this criteria can be readily determined by simple and routine testing. Ordinarily, a medical grade adhesive applied to a thickness ranging from about 1.0 mils to about 3.5 mils and preferably from about 2.0 mils to about 2.5 mils (depending, of course, on the thickness of the backing layer) will meet this requirement reasonably well. Adhesive layer 14 may include holes or a permeable material to allow moisture to escape and provide oxygen to the skin.

Transducer material 16 can be formed from any transducer material known to one skilled in the art, e.g., an air backed quarter wave matched transducer material, polyvinylidene fluoride material (PVDF), etc. Preferably, transducer material 16 can be those disclosed in International PCT Application No. PCT/US99/06650, filed on March 26, 1999, the contents of which are incorporated by reference herein. For example, transducer material 16 can be formed from one or more fibers extruded from a composition containing a piezoelectric material. The extruded fibers can be knitted, woven or braided in 1, 2 or 3 dimensions to provide a structure that includes spaces which can be filled with a polymeric material to form a composite. Fibers made of piezoelectric material suitable for use herein can be prepared, for example, by using a viscous suspension spinning process and are available from Advanced Cerametrics

Incorporated (Lambertville, NJ). Suitable piezoelectric materials for use in the fibers include PZT powders commercially available from Morgan Matroc, Inc., ceramic, lead zirconate titanate $\text{Pb}(\text{Zr},\text{Ti})\text{O}_3$, lead metaniobate $\text{Pb}(\text{Nb}_2\text{O}_6)$, modified lead titanate PbTi_3 such as $(\text{Pb},\text{Ca})\text{TiO}_3$ and $(\text{Pb},\text{Sm})\text{TiO}_3$, barium titanate BaTiO_3 , PMN-PT(1-
5 $x)\text{Pb}(\text{Mg}_{1/2},\text{Nb}_{1/2})\text{O}_3$ - $x\text{PbTiO}_3$, PZN-PT/BT $\text{Pb}(\text{Zn}_{1/2},\text{Nb}_{1/2})\text{O}_3$ - $x\text{PbTiO}_3$ - BaTiO_3 , (1-
 $x)\text{Pb}(\text{Zn}_{1/2},\text{Nb}_{1/2})\text{O}_3$ - $x(y\text{PbTiO}_3-(1-y)\text{PbZrO}_3)$ and the like. In particularly useful embodiments, the extruded fibers are knitted, woven, braided or non-woven to form a fiber sheet. Preferably, a simple woven fabric is used as the fiber sheet. Optionally, the individual fibers in the fiber sheets can be coated with a film-forming polymer
10 solution to improve the strength and wear resistance of the individual fibers prior to weaving, knitting and braiding. Suitable solutions of film-forming material are known to those in the textile art. By way of example, the solution can contain a mixture of a polyvinyl alcohol and polyvinyl acetate as a major component thereof and polyethylene glycol as a minor component thereof.

15 Transducer material 16 can be of varying shapes and sizes depending, of course, on the size of the wound to be treated. This can be determined according to simple and routine experimental testing. Ordinarily, the thickness of transducer material 16 will range from about 0.1 mils to about 5 mils and preferably from about 1.5 mils to about 3.0 mils with the width of material 16 ranging from about 0.1 inch to about 1.5 inches
20 and preferably from about 0.5 inch to about 1 inch.

Electrode surfaces 19a and 19b are applied to opposite surfaces of transducer material 16. Typically, electrode surface 19a will be applied onto one surface of the

transducer material by techniques known to one skilled in the art, e.g., utilizing photolithographic techniques. In general, electrode surface 19b will be applied to, and substantially coextensive with, the other surface of the transducer material. Electroding can be achieved employing techniques known to one skilled in the art, e.g., sputtering, painting. Materials useful in forming the electrode surfaces include copper, silver, nickel, gold, alloys, mixtures thereof and the like. Typically, electrode surface 19a will be positively charged and the other electrode surface 19b will serve as a ground.

Once electrode surfaces 19a and 19b have been applied, matching layer 15 can then be applied to, and substantially coextensive with, electrode surface 19b.

Techniques for applying the matching layer are within the purview of one skilled in the art. Generally, the thickness of the matching layer can be chosen to correspond to one-quarter of the wavelength in the matching layer at the operating frequency of the transducer array. The acoustic impedance of the matching layer will preferably range from about 2.0 to about 7.0 MRayls.

Matching layer 15 will ordinarily be formed from a polymeric material, and optionally, a filler. The polymeric material should have good compatibility with the components of the composite, biocompatibility and flexibility. Useful polymeric materials include thermoplastics such as high density polyethylenes, polymethyl methacrylates, polypropylenes, polybutylene terephthalates, polycarbonates, polyurethanes such as CA 118 and CA 128 available from Morton Chemical and estane polyester, and the like; thermosets such as epoxies such as Spurr epoxy and Stycast 80, and the like; and rubbers such as silicone rubbers such as dispersion 236 available from

Dow Corning and RTV-141 available from Rhone-Poulenc, Inc. and the like. A preferred polymeric material for use herein is Stycast 1365-65. Because the acoustic impedance of many polymeric materials is less than the preferred range of 2.0 - 7.0 MRayls, it is necessary to increase the acoustic impedance of the polymer.

5 Accordingly, one or more fillers can be incorporated therein. Suitable fillers include PZT, tungsten, alumina, silica glass, tungsten carbide, titanium, glass powder and the like with glass powder being preferred. The size of the filler particles should be in the range of about 0.1 to about 50 microns and preferably from about 0.5 to about 5 microns. The amount of filler employed will be that amount necessary to impart the
10 desired acoustic impedance. Normally, from about 2 to about 50 percent filler by volume and preferably from about 5 to about 30 volume percent filler is employed.

Coupling pad 18 can be selected from any coupling material known to one skilled in the art. A preferred coupling material for use herein is a hydrogel pad.

Coupling pad 18 can have a substantially planar surface as depicted in FIG. 1.

15 Alternatively, coupling pad 18 can be configured, for example, as a wedge, i.e., possessing a non-planar surface, as depicted in FIG. 2A and FIG. 2B. Thus, when employing a coupling pad 18 configured as, for example, a wedge, the longitudinal waves are to be transmitted from the transducer off-axis, at an angle equal to or slightly greater than the critical angle, depending on Poisson's ratio for soft tissue, where the
20 longitudinal waves are converted completely into shear waves (modal conversion) for therapeutic ultrasonic stimulation and treatment at the site of the wound.

Since the delivery of ultrasound to a target injury requires an efficient coupling

path between the transducer material and the patient's skin and soft tissue, a material for ultrasound coupling is typically employed to effect a proper interface for propagating acoustic energy into the patient's body. Commonly used materials include sonically conductive materials such as, for example, glycerol, water, oils, lotions, etc., which are applied onto the coupling pad prior to bandage 10 being placed on the patient's body.

Ultrasound bandage 10 is typically employed in an ultrasound bandage assembly as generally depicted in FIG. 3. Ultrasound bandage assembly 20 will include at least one or more ultrasound bandages 10 having connector assemblies 24 with leads 26 for coupling ultrasound transducers 16 to a portable main operating unit (MOU). Connector assemblies 24 include detachable connectors 22 for detachably connecting leads 26 to transducers 16 which is mounted on adhesive layer 14 (see FIG. 4). Connectors 22 are operatively coupled to transducers 16 and are preferably of the quick-connected type such that leads 26 may be detached and reused while ultrasound bandages 10 can be disposed of. The MOU supplies powers and provides signals for controlling transducers 16. In one embodiment, the MOU can be a commercially available device such as, for example, an SAFHS 2000 available commercially from Exogen, Inc. (Piscataway, NJ). A preferred MOU is described in further detail in U.S. Application Serial No. 09/040,157 which is incorporated by reference herein. The MOU preferably includes a processor which could be a microprocessor used in conjunction with transducers 16. The processor generates control signals which are amplified by an output driver to the desired power level and imparted to the transducers

16.

The ultrasound transducer array bandages of the present invention can be obtained by forming an array of a plurality of the foregoing transducer materials. The transducer array bandage 30 can be formed, for example, by disposing an arrangement of transducer materials 32 in adjacent relation to one another to define spaces 34 therebetween as generally depicted in FIG. 5. It is to be understood that the transducer materials 32 can be of varying sizes when forming the array bandage described herein. In general, the transducer materials 32 can be placed close together or spaced further apart and the spacings need not be uniform or in perfect alignment.

The transducer materials 32 are disposed on or within at least a portion of adhesive layer 36 which is applied to, and substantially coextensive with, backing layer 38. Useful materials for forming backing layer 38 and adhesive layer 36 can be any of the aforementioned materials. Typically, the spaces between transducer materials 32 will range from about 0.5 mm to about 10 mm and preferably from about 1 mm to about 3 mm. The dimensions of the array will ordinarily range from about 0.5 inch to about 6 inches wide and from about 0.5 inch to about 12 inches long. The thickness of the array can effect the frequency of operation and will ordinarily range from about 0.05 mm to about 10 mm. It should, of course, be understood that the array can include transducer materials with different frequencies of operation. These differences in frequency of operation can be achieved by employing transducer materials of different thicknesses.

Electrode surfaces 39a and 39b can be applied to, and substantially coextensive

with, each transducer material 32 in the array. Once the electrode surfaces have been applied, matching layers 33 can then be applied to, and substantially coextensive with, electrode surfaces 39b. Useful materials for forming the electrode surfaces and the matching layer can be any of the aforementioned materials.

5 Coupling pad 35 can be, for example, a hydrogel pad, and is typically applied to, and substantially coextensive with, each matching layer 33, i.e., the array. Alternatively, coupling pad 35 can be applied to, and substantially coextensive with, each matching layer 33 (not shown). In use, coupling pad 35 can have a substantially planar surface as depicted in FIG. 5. Alternatively, coupling pad 35 can be configured,
10 for example, as a wedge, i.e., possessing a non-planar surface, as depicted in FIG. 6A and FIG. 6B. Thus, when employing a coupling pad 35 configured as, for example, a wedge, the longitudinal waves are to be transmitted from the transducers off-axis, at an angle equal to or slightly greater than the critical angle, depending on Poisson's ratio for soft tissue, where the longitudinal waves are converted completely into shear waves
15 (modal conversion) for therapeutic ultrasonic stimulation and treatment at the site of the wound. Release liners 37a and 37b seal and protect adhesive layer 36, transducer materials 32 and coupling pad 35 during the residency of ultrasound transducer array bandage 30 within its package with release liner 37a overlapping release liner 37b.

20 Once the ultrasound transducer array bandage 30 has been formed, connector assemblies 40 with leads 42 for coupling ultrasound transducers 32 to a portable main operating unit (MOU) are applied to the transducers 32 to form an ultrasound transducer array bandage assembly 44 as generally depicted in FIG.7. Connector

assemblies 40 include detachable connectors 48 for detachably connecting leads 42 to transducers 32 which is mounted on adhesive layer 36. Connectors 48 are operatively coupled to transducers 32 and are preferably of the quick-connected type such that leads 42 may be detached and reused while ultrasound transducer array bandages 44 can be disposed of.

The ultrasound bandages and ultrasound transducer array bandages of this invention can also possess a protective covering (not shown) instead of release liners 17a and 17b and 37a and 37b, respectively. Covers of this kind are known from U.S. Patent No. 4,627,429, the contents of which are incorporated by reference herein. In general, the protective covering can be made, for example, of a heat-sealable aluminum foil film laminate with the heat-sealable surface down. A formed cup, dome or square in the cover allows room for the transducer materials and coupling pad with the other portion of the cover being placed over the adhesive layer.

The ultrasound bandages and ultrasound transducer array bandages of this invention can be manufactured in a variety of sizes and shapes, e.g., rectangular, oval, etc., and can be planar or three-dimensional. Additionally, the ultrasound bandages and ultrasound transducer array bandages used herein can contain indicia thereon, e.g., text, color, etc., to indicate the direction of the transducer so that the ultrasonic waves can be directed toward the wound as depicted in FIG. 8.

The ultrasound bandages and ultrasound transducer array bandages of this invention are particularly useful in therapeutic applications. In general, the foregoing bandages will be applied adjacent to, or directly over, the wound to facilitate the

transfer of acoustic energy to promote the healing of wounds. As noted above, the term "wound" as used herein has a broad meaning as generally encompassing addressing damage to, and repair of, or restoration of soft tissue or wounds to the skin such as abrasions and lacerations. The present invention can be used, for example, to prevent surgical adhesions by stimulating the proper repair of surgical incisions. It can also prevent or arrest wound dehiscence by promoting vascularization at the surfaces adjacent surgical incisions. It can also be used in cosmetic surgery, for example, by enhancing the healing of hair transplants, or by directly stimulating regeneration of cells.

In general, once the acoustic energy enters the body, it passes into internal body tissue and/or fluids. The acoustic energy, in the form of ultrasonic pulses, is reflected off the surface of underlying bone or other ultrasound reflective material and the reflected ultrasound travels toward at least part of the internal surface or underside of the wound. Healing of the wound at the internal surface by the generation of epithelial cells is enhanced via the acoustic stimulation.

Preferably, a low frequency signal which is present as the modulation of the carrier frequency is transmitted as a longitudinal acoustic wave from the transducer material, through interposed soft tissue, and onto the surface of the bone. The longitudinal wave incident on the bone surface, or other designated reflection sites in the body, is reflected toward the internal surface of the wound as longitudinal and/or shear waves. These reflected waves flooding a region of the internal surface of the wound increase vascularization at the internal surface of the wound thus enhancing

growth of epithelial cells. The epithelial cell growth represents healing of the wound. The technique thus promotes healing of the wound from the internal surface of the wound.

The number, position and size of ultrasonic bandages used at the external skin location are chosen based on the size and position of the wound and the relative position and proximity of the bone from which the ultrasonic waves are reflected. Thus, more than one ultrasound bandage or ultrasound transducer array bandage can be employed at the site of the wound. For example, bandages 10 can be employed about a wound 50 on a body 52 and positioned and configured to provide enhanced healing treatment to wound 50 as generally depicted in FIG. 9 and FIG. 10. A portable MOU is shown for providing power and control to transducers 16 via connectors 26. Additionally, for example, ultrasound transducer array bandage 30 having a plurality of transducer materials 32 can be disposed over a wound 54 on a body 56 for treatment thereof with a portable MOU connected thereto.

Typically, the frequency of the acoustic energy applied during treatment will be in the range of from about 20 kHz to about 10 MHz and preferably from about 0.5 to about 5 MHz. Features characterizing the frequency of the acoustic energy are disclosed in U.S. Patent No. 5,520,612, the contents of which are incorporated by reference herein. It is to be understood that multiple sections of the human anatomy can be treated with multiple ultrasound bandages or ultrasound transducer array bandages at the same time. Thus, for example, in the case of an individual suffering from both an abrasion to the arm and an abrasion to the leg, an ultrasound bandage or

ultrasound transducer array bandage can be applied to the arm while a second ultrasound bandage or ultrasound transducer array bandage is being applied to the section of the leg suffering from the wound. The transmit frequency and acoustic energy applied to each section can vary according to the foregoing ranges.

5 When applying the foregoing bandages to the section of the human anatomy in need of therapeutic assistance, it is advantageous to apply a coupling gel to the transducer material prior to its employment on the part of the body. Additionally, when employing the foregoing ultrasound transducer array bandages, it may be desirable in certain cases to use selective energization of the transducer materials in the
10 array such that certain elements will generate acoustic energy while other elements will not. This will permit the spatial, temporal, and frequency control of the distribution of acoustic energy in the body. Techniques for altering the acoustic energy of the transducer materials are disclosed in U.S. Patent No. 5,520,612.

15 Although the present invention has been described in preferred forms with a certain degree of particularity, many changes and variations are possible therein and will be apparent to those skilled in the art after reading the foregoing description. It is therefore to be understood that the present invention may be practiced otherwise than as specifically described herein without departing from the spirit and scope thereof.

WHAT IS CLAIMED IS:

1. An ultrasound bandage which comprises:
 - a) a backing layer possessing upper and lower surfaces;
 - b) an adhesive layer applied to, and substantially coextensive with, the
5 lower surface of the backing layer; and,
 - c) a transducer material disposed on at least a portion of the adhesive layer.
2. The ultrasound bandage of Claim 1 wherein the backing layer is a polyurethane film.
3. The ultrasound bandage of Claim 1 wherein the adhesive layer is
10 fabricated from a material selected from the group consisting of polyacrylic resin, polyvinylether resin and polyurethane resin.
4. The ultrasound bandage of Claim 1 wherein the transducer material comprises a fiber sheet formed from a composition containing a piezoelectric material.
5. The ultrasound bandage of Claim 4 wherein the fiber sheet is a fabric
15 woven from one or more fibers containing a piezoelectric material.
6. The ultrasound bandage of Claim 4 wherein the piezoelectric material is selected from the group consisting of PZT powders, ceramic, PVDF, lead zirconate titanate $\text{Pb}(\text{Zr}, \text{Ti})\text{O}_3$, lead metaniobate $\text{Pb}(\text{Nb}_2\text{O}_6)$, modified lead titanate PbTi_3 , $(\text{Pb}, \text{Ca})\text{TiO}_3$, $(\text{Pb}, \text{Sm})\text{TiO}_3$, barium titanate BaTiO_3 , $\text{PMN-PT}(1-x)\text{Pb}(\text{Mg}_{1/2}, \text{Nb}_{1/2})\text{O}_3$ -
20 $x\text{PbTiO}_3$, $\text{PZN-PT/BT } \text{Pb}(\text{Zn}_{1/2}, \text{Nb}_{1/2})\text{O}_3$ - $x\text{PbTiO}_3$ - BaTiO_3 , $(1-x)\text{Pb}(\text{Zn}_{1/2}, \text{Nb}_{1/2})\text{O}_3$ -
 $x(y\text{PbTiO}_3-(1-y)\text{PbZrO}_3)$ and mixtures thereof.

7. The ultrasound bandage of Claim 4 wherein the fiber sheet is knitted, braided or woven from extruded fibers containing a piezoelectric material.

8. The ultrasound bandage of Claim 4 wherein the extruded fibers possess a coating formed thereon.

5 9. The ultrasound bandage of Claim 8 wherein the coating comprises a film-forming polymer solution.

10. The ultrasound bandage of Claim 9 wherein the film-forming polymer solution contains a mixture of a polyvinyl alcohol and polyvinyl acetate as a major component thereof and polyethylene glycol as a minor component thereof.

10 11. The ultrasound bandage of Claim 1 further comprising an electrode surface applied to, and substantially coextensive with, opposite surfaces of the transducer material and a matching layer applied to, and substantially coextensive with, one of the electrode surfaces.

15 12. The ultrasound bandage of Claim 11 wherein the matching layer comprises a polymeric material and optionally a filler.

13. The ultrasound bandage of Claim 12 wherein the polymeric material is selected from the group consisting of thermoplastics, thermosets, rubbers, epoxy and mixtures thereof.

20 14. The ultrasound bandage of Claim 12 wherein the matching layer includes a filler selected from the group consisting of PZT, tungsten, alumina, silica glass, tungsten carbide and titanium.

15. The ultrasound bandage of Claim 12 wherein the matching layer includes glass powder as a filler.

16. The ultrasound bandage of Claim 11 wherein the matching layer has an acoustic impedance of from about 2.0 to about 7.0 MRayls.

5 17. The ultrasound bandage of Claim 11 further comprising a coupling pad applied to, and substantially coextensive with, the matching layer.

18. The ultrasound bandage of Claim 17 wherein the coupling pad is a hydrogel pad.

10 19. The ultrasound bandage of Claim 17 wherein the coupling pad is configured as a wedge to direct a longitudinal wave from the transducer material off-axis for to an internal designated reflection site and/or for modal conversion.

20. The ultrasound bandage of Claim 1 further comprising connector assemblies having connectors and leads, the connectors detachably connect leads to the transducer material and the leads are coupled to a portable main operating unit.

15 21. The ultrasound bandage of Claim 19 further comprising a cover covering the adhesive layer and the coupling pad and being applied to the adhesive layer.

22. A method for manufacturing an ultrasound bandage which comprises:

- a) providing a backing layer possessing upper and lower surfaces;
- b) applying an adhesive layer to, and substantially coextensive with, the
20 lower surface of the backing layer; and,
- c) disposing a transducer material on at least a portion of the adhesive layer.

23. The method of Claim 22 wherein the backing layer is a polyurethane film.

24. The method of Claim 22 wherein the adhesive layer is fabricated from a material selected from the group consisting of polyacrylic resin, polyvinylether resin
5 and polyurethane resin.

25. The method of Claim 22 wherein the transducer material comprises a fiber sheet formed from a composition containing a piezoelectric material.

26. The method of Claim 25 wherein the fiber sheet is a fabric woven from one or more fibers containing a piezoelectric material.

10 27. The method of Claim 25 wherein the piezoelectric material is selected from the group consisting of PZT powders, ceramic, PVDF, lead zirconate titanate $\text{Pb}(\text{Zr},\text{Ti})\text{O}_3$, lead metaniobate $\text{Pb}(\text{Nb}_2\text{O}_6)$, modified lead titanate PbTi_3 , $(\text{Pb},\text{Ca})\text{TiO}_3$, $(\text{Pb},\text{Sm})\text{TiO}_3$, barium titanate BaTiO_3 , $\text{PMN-PT}(1-x)\text{Pb}(\text{Mg}_{1/2},\text{Nb}_{1/2})\text{O}_3-x\text{PbTiO}_3$, $\text{PZN-PT/BT Pb}(\text{Zn}_{1/3},\text{Nb}_{2/3})\text{O}_3-x\text{PbTiO}_3-\text{BaTiO}_3$, $(1-x)\text{Pb}(\text{Zn}_{1/3},\text{Nb}_{2/3})\text{O}_3-x(y\text{PbTiO}_3-(1-y)\text{PbZrO}_3)$ and mixtures thereof.
15

28. The method of Claim 25 wherein the extruded fibers possess a coating formed thereon.

29. The method of Claim 28 wherein the coating comprises a film-forming polymer solution.

20 30. The method of Claim 29 wherein the film-forming polymer solution contains a mixture of a polyvinyl alcohol and polyvinyl acetate as a major component thereof and polyethylene glycol as a minor component thereof.

31. The method of Claim 22 further comprising an electrode surface applied to, and substantially coextensive with, opposite surfaces of the transducer material and a matching layer applied to, and substantially coextensive with, one of the electrode surfaces.

5 32. The method of Claim 31 wherein the matching layer comprises a polymeric material and optionally a filler.

33. The method of Claim 32 wherein the polymeric material is selected from the group consisting of thermoplastics, thermosets, rubbers, epoxy and mixtures thereof.

10 34. The method of Claim 32 wherein the matching layer includes a filler selected from the group consisting of PZT, tungsten, alumina, silica glass, tungsten carbide and titanium.

35. The method of Claim 32 wherein the matching layer includes glass powder as a filler.

15 36. The method of Claim 31 wherein the matching layer has an acoustic impedance of from about 2.0 to about 7.0 MRayls.

37. The method of Claim 31 further comprising applying a coupling pad to, and substantially coextensive with, the matching layer.

38. The method of Claim 37 wherein the coupling pad is a hydrogel pad.

20 39. The method of Claim 37 wherein the coupling pad is configured as a wedge to direct a longitudinal wave from the transducer material off-axis for to an internal designated reflection site and/or for modal conversion.

40. The method of Claim 22 further comprising connecting connector assemblies having connectors and leads to the transducer material of the ultrasonic bandage.

- 5 41. An ultrasound transducer array bandage which comprises:
- a) a backing layer possessing upper and lower surfaces;
 - b) an adhesive layer applied to, and substantially coextensive with, the lower surface of the backing layer;
 - c) an array comprising a plurality of transducer materials arranged in adjacent relation to define spaces therebetween, the array being disposed on at least a
10 portion of the adhesive layer; and,
 - d) a connector assembly applied to the array.

42. The ultrasound transducer array bandage of Claim 41 wherein the backing layer is a polyurethane film.

- 15 43. The ultrasound transducer array bandage of Claim 41 wherein the adhesive layer is fabricated from a material selected from the group consisting of polyacrylic resin, polyvinylether resin and polyurethane resin.

44. The ultrasound transducer array bandage of Claim 41 wherein each transducer material comprises a fiber sheet formed from a composition containing a
20 piezoelectric material.

45. The ultrasound transducer array bandage of Claim 44 wherein the fiber sheet is a fabric woven from one or more extruded fibers containing a piezoelectric

material.

46. The ultrasound transducer array bandage of Claim 44 wherein the piezoelectric material is selected from the group consisting of PZT powders, ceramic, PVDF, lead zirconate titanate $\text{Pb}(\text{Zr}, \text{Ti})\text{O}_3$, lead metaniobate $\text{Pb}(\text{Nb}_2\text{O}_6)$, modified lead titanate PbTi_3 , $(\text{Pb}, \text{Ca})\text{TiO}_3$, $(\text{Pb}, \text{Sm})\text{TiO}_3$, barium titanate BaTiO_3 , PMN-PT(1-x) $\text{Pb}(\text{Mg}_{1/2}, \text{Nb}_{1/2})\text{O}_3$ -x PbTiO_3 , PZN-PT/BT $\text{Pb}(\text{Zn}_{1/2}, \text{Nb}_{1/2})\text{O}_3$ -x PbTiO_3 - BaTiO_3 , (1-x) $\text{Pb}(\text{Zn}_{1/2}, \text{Nb}_{1/2})\text{O}_3$ -x(y PbTiO_3 -(1-y) PbZrO_3) and mixtures thereof.

47. The ultrasound transducer array bandage of Claim 44 wherein the fiber sheet is knitted, braided or woven from extruded fibers containing a piezoelectric material.

48. The ultrasound transducer array bandage of Claim 44 wherein the extruded fibers possess a coating formed thereon.

49. The ultrasound transducer array bandage of Claim 48 wherein the coating comprises a film-forming polymer solution.

50. The ultrasound transducer array bandage of Claim 49 wherein the film-forming polymer solution contains a mixture of a polyvinyl alcohol and polyvinyl acetate as a major component thereof and polyethylene glycol as a minor component thereof.

51. The ultrasound transducer array bandage of Claim 41 further comprising an electrode surface applied to, and substantially coextensive with, opposite surfaces of each transducer material and a matching layer applied to, and substantially coextensive with, one of the electrode surfaces.

52. The ultrasound transducer array bandage of Claim 51 wherein the matching layer comprises a polymeric material and optionally a filler.

53. The ultrasound transducer array bandage of Claim 52 wherein the
5 polymeric material is selected from the group consisting of thermoplastics, thermosets, rubbers, epoxy and mixtures thereof.

54. The ultrasound transducer array bandage of Claim 52 wherein the matching layer includes a filler selected from the group consisting of PZT, tungsten, alumina, silica glass, tungsten carbide and titanium.

10 55. The ultrasound transducer array bandage of Claim 52 wherein the matching layer includes glass powder as a filler.

56. The ultrasound bandage of Claim 51 wherein the matching layer has an acoustic impedance of from about 2.0 to about 7.0 MRayls.

57. The ultrasound transducer array bandage of Claim 51 further comprising
15 a coupling pad applied to, and substantially coextensive with, the matching layer.

58. The ultrasound transducer array bandage of Claim 57 wherein the coupling pad is a hydrogel pad.

59. The ultrasound transducer array bandage of Claim 57 wherein the coupling pad is configured as a wedge to direct a longitudinal wave from each
20 transducer material off-axis for to an internal designated reflection site and/or for modal conversion.

60. The ultrasound transducer array bandage of Claim 41 wherein the connector assemblies comprise connectors and leads, the connectors detachably connect leads to the array and the leads are coupled to a portable main operating unit.

5 61. The ultrasound transducer array bandage of Claim 41 further comprising a cover covering the adhesive layer and the coupling pad and being applied to the adhesive layer.

62. A method for manufacturing an ultrasound transducer array bandage which comprises:

- 10 a) providing a backing layer possessing upper and lower surfaces;
- b) applying an adhesive layer to, and substantially coextensive with, the lower surface of the backing layer;
- c) disposing an array comprising a plurality of transducer materials arranged in adjacent relation to define spaces therebetween on at least a portion of the adhesive layer; and,
- 15 d) applying a connector assembly to the array.

63. The method of Claim 62 wherein the backing layer is a polyurethane film.

64. The method of Claim 62 wherein the adhesive layer is fabricated from a material selected from the group consisting of polyacrylic resin, polyvinylether resin and polyurethane resin.

20

65. The method of Claim 62 wherein each transducer material comprises a fiber sheet formed from a composition containing a piezoelectric material.

66. The method of Claim 65 wherein the piezoelectric material is selected from the group consisting of PZT powders, ceramic, PVDF, lead zirconate titanate $\text{Pb}(\text{Zr},\text{Ti})\text{O}_3$, lead metaniobate $\text{Pb}(\text{Nb}_2\text{O}_6)$, modified lead titanate PbTi_3 , $(\text{Pb},\text{Ca})\text{TiO}_3$, $(\text{Pb},\text{Sm})\text{TiO}_3$, barium titanate BaTiO_3 , $\text{PMN-PT}(1-x)\text{Pb}(\text{Mg}_{1/2},\text{Nb}_{1/2})\text{O}_3-x\text{PbTiO}_3$, PZN-PT/BT $\text{Pb}(\text{Zn}_{1/2},\text{Nb}_{1/2})\text{O}_3-x\text{PbTiO}_3-\text{BaTiO}_3$, $(1-x)\text{Pb}(\text{Zn}_{1/2},\text{Nb}_{1/2})\text{O}_3-x(y\text{PbTiO}_3-(1-y)\text{PbZrO}_3)$ and mixtures thereof.

67. The method of Claim 65 wherein the fiber sheet is a fabric woven from one or more fibers containing a piezoelectric material.

68. The method of Claim 65 further comprising the step of forming the fiber sheet by knitting, braiding or weaving the extruded fibers.

69. The method of Claim 68 further comprising applying a coating to the extruded fibers prior to forming the fiber sheet.

70. The method of Claim 69 wherein the coating comprises a film-forming polymer solution.

71. The method of Claim 70 wherein the film-forming polymer solution contains a mixture of a polyvinyl alcohol and polyvinyl acetate as a major component thereof and polyethylene glycol as a minor component thereof.

72. The method of Claim 62 further comprising an electrode surface applied to, and substantially coextensive with, opposite surfaces of each transducer material and a matching layer applied to, and substantially coextensive with, one of the electrode surfaces.

73. The method of Claim 72 wherein the matching layer comprises a polymeric material and optionally a filler.

74. The method of Claim 73 wherein the polymeric material is selected from the group consisting of thermoplastics, thermosets, rubbers, epoxy and mixtures thereof.

75. The method of Claim 73 wherein the matching layer includes a filler selected from the group consisting of PZT, tungsten, alumina, silica glass, tungsten carbide and titanium.

76. The method of Claim 73 wherein the matching layer includes glass powder as a filler.

77. The ultrasound bandage of Claim 72 wherein the matching layer has an acoustic impedance of from about 2.0 to about 7.0 MRayls.

78. The method of Claim 72 further comprising applying a coupling pad to, and substantially coextensive with, the matching layer

79. The method of Claim 78 wherein the coupling pad is a hydrogel pad.

80. The method of Claim 78 wherein the coupling pad is configured as a wedge to direct a longitudinal wave from each transducer material off-axis for to an internal designated reflection site and/or for modal conversion.

81. The method of Claim 62 wherein the connector assemblies comprise connectors and leads.

82. A method for accelerating the healing of wounds comprising:
- a) positioning at least one ultrasound bandage adjacent to a body at the site of a wound;
 - b) the ultrasound bandage comprising:
 - I) a backing layer possessing upper and lower surfaces;
 - ii) an adhesive layer applied to, and substantially coextensive with, the lower surface of the backing layer; and,
 - iii) a transducer material disposed on at least a portion of the adhesive layer; and,
 - c) causing the transducer material to generate ultrasonic pulses.
83. The method of Claim 82 wherein at least one ultrasound bandage is positioned adjacent to a body at a plurality of sites of wounds.
84. The method of Claim 82 further comprising applying an electrode surface to, and substantially coextensive with, opposite surfaces of the transducer material, applying a matching layer to, and substantially coextensive with, one of the electrode surfaces and applying a coupling pad configured as a wedge to the matching layer.
85. A method for accelerating the healing of wounds comprising:
- a) positioning at least one ultrasound transducer array bandage adjacent to a body at the site of a wound;
 - b) the ultrasound transducer array bandage comprising:
 - I) a backing layer possessing upper and lower surfaces;

ii) an adhesive layer applied to, and substantially coextensive with, the lower surface of the backing layer; and,

iii) an array comprising a plurality of transducer materials arranged in adjacent relation to define spaces therebetween, the array being disposed on at least a portion of the adhesive layer and,

c) causing the plurality transducer materials to generate ultrasonic pulses.

86. The method of Claim 85 wherein at least one ultrasound transducer array bandage is positioned adjacent to a body at a plurality of sites of wounds.

87. The method of Claim 85 further comprising applying an electrode surface to, and substantially coextensive with, opposite surfaces of each transducer material, applying a matching layer to, and substantially coextensive with, one of the electrode surfaces and applying a coupling pad configured as a wedge to the matching layer.

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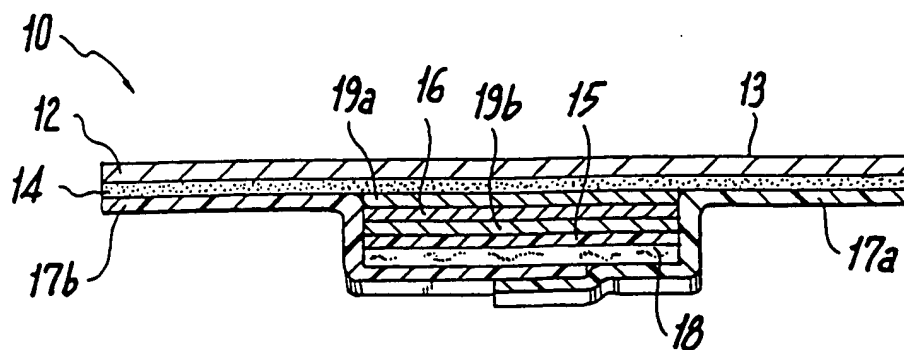


Fig. 1

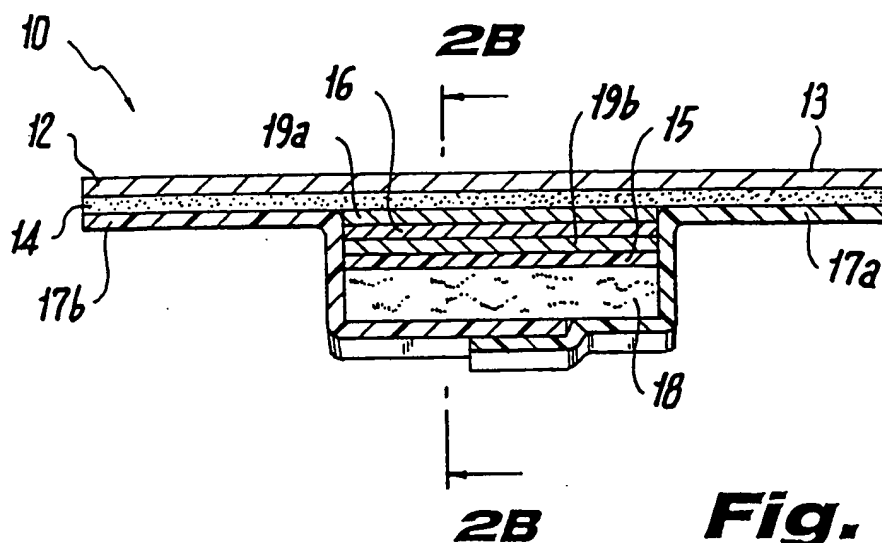


Fig. 2A

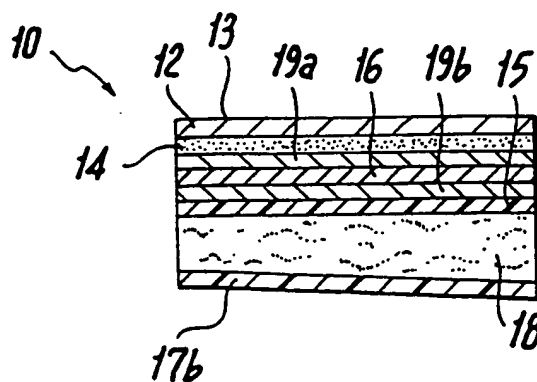
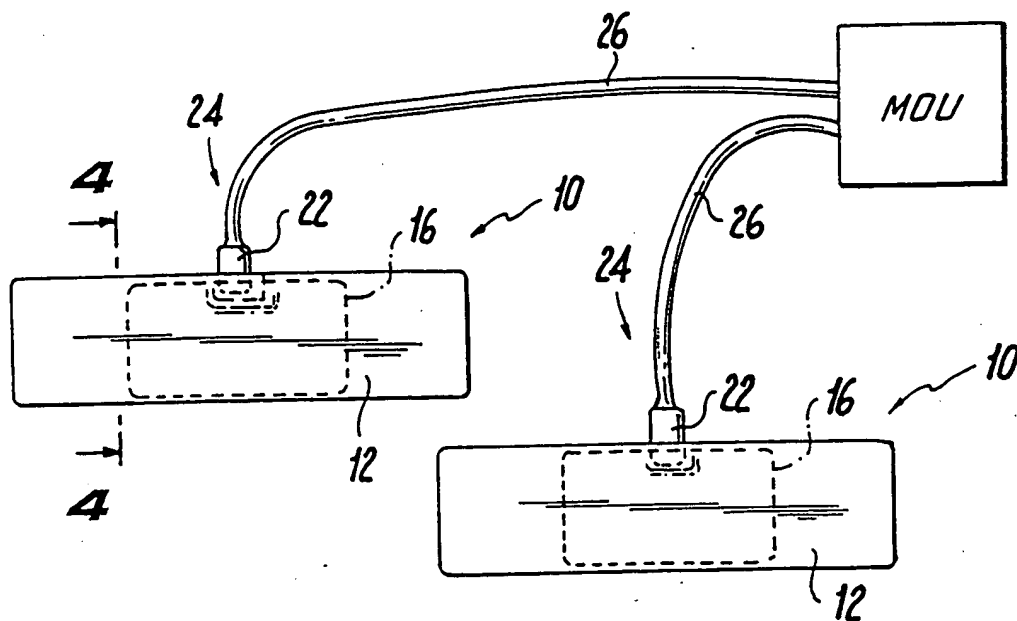
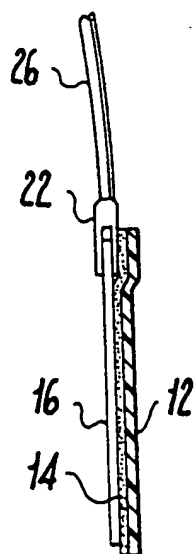
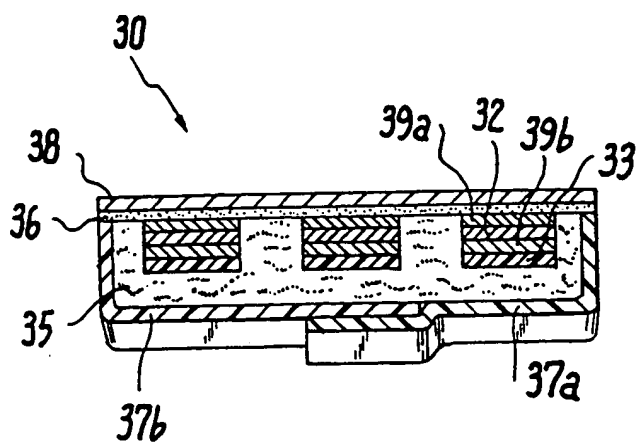
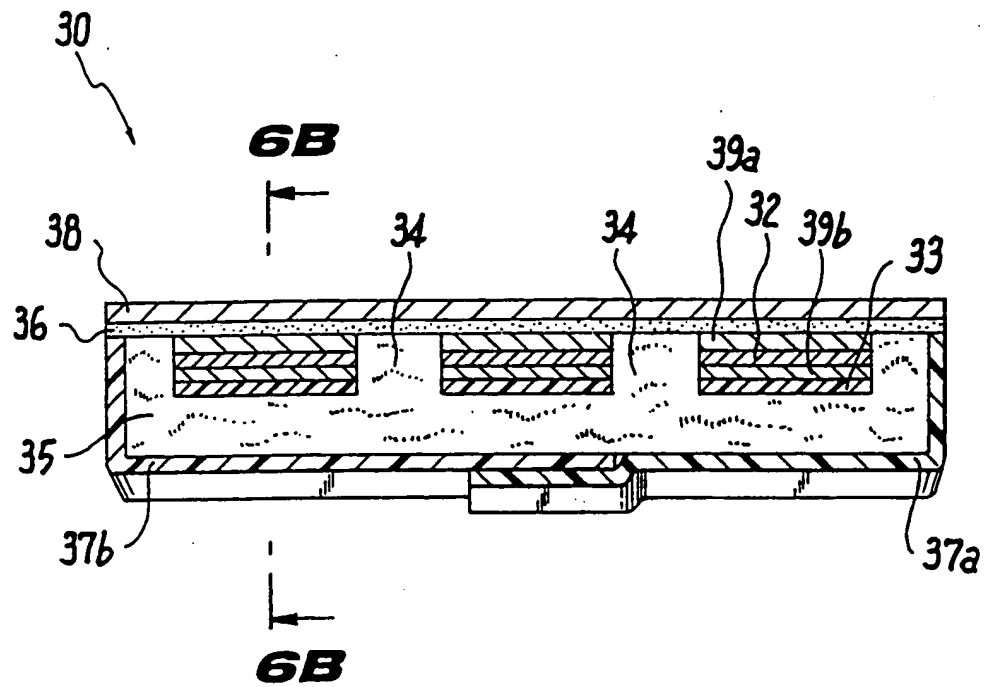
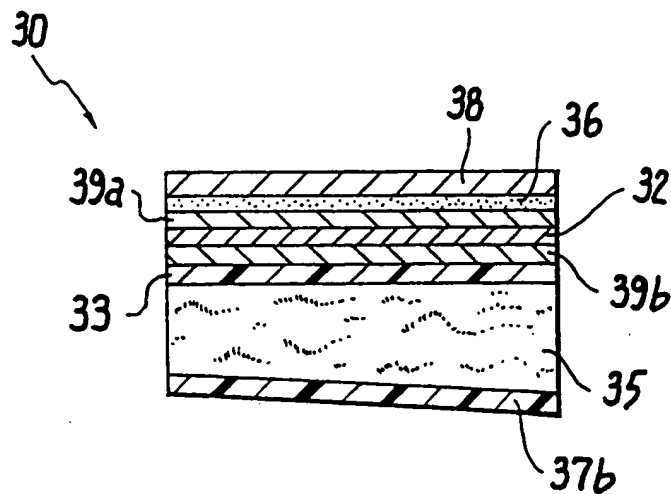


Fig. 2B

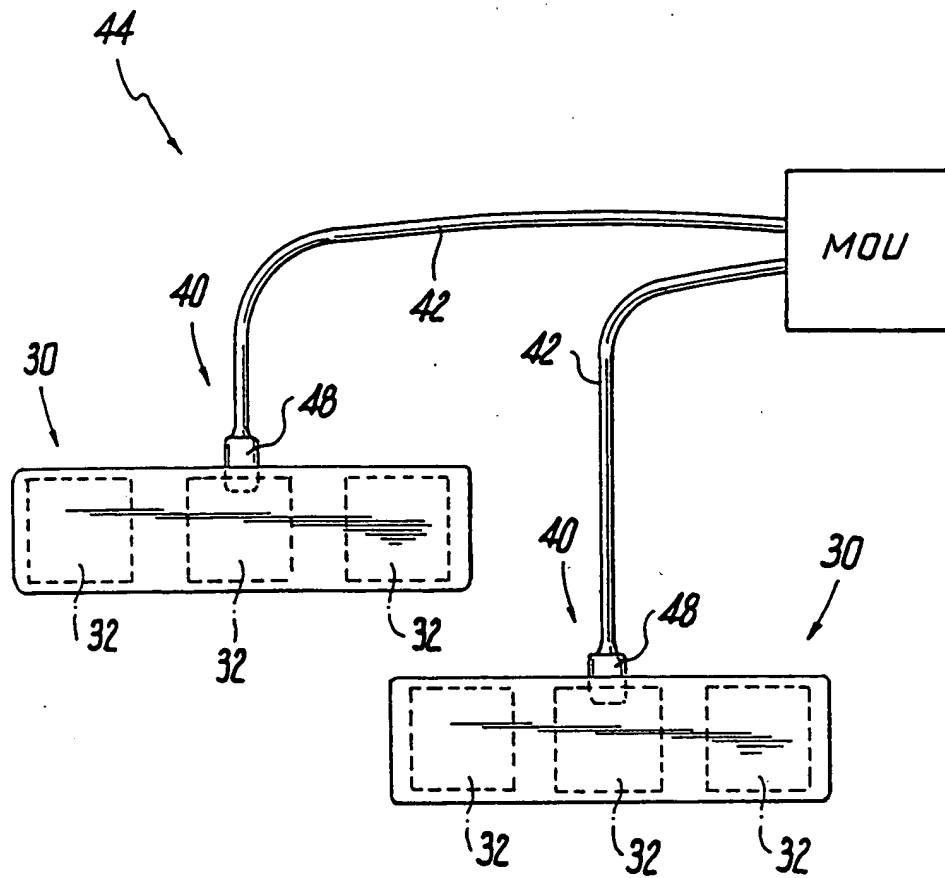
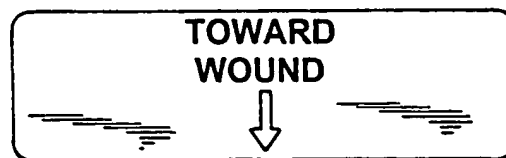
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**Fig. 3****Fig. 4****Fig. 5**

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**Fig. 6A****Fig. 6B**

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**Fig. 7****Fig. 8**

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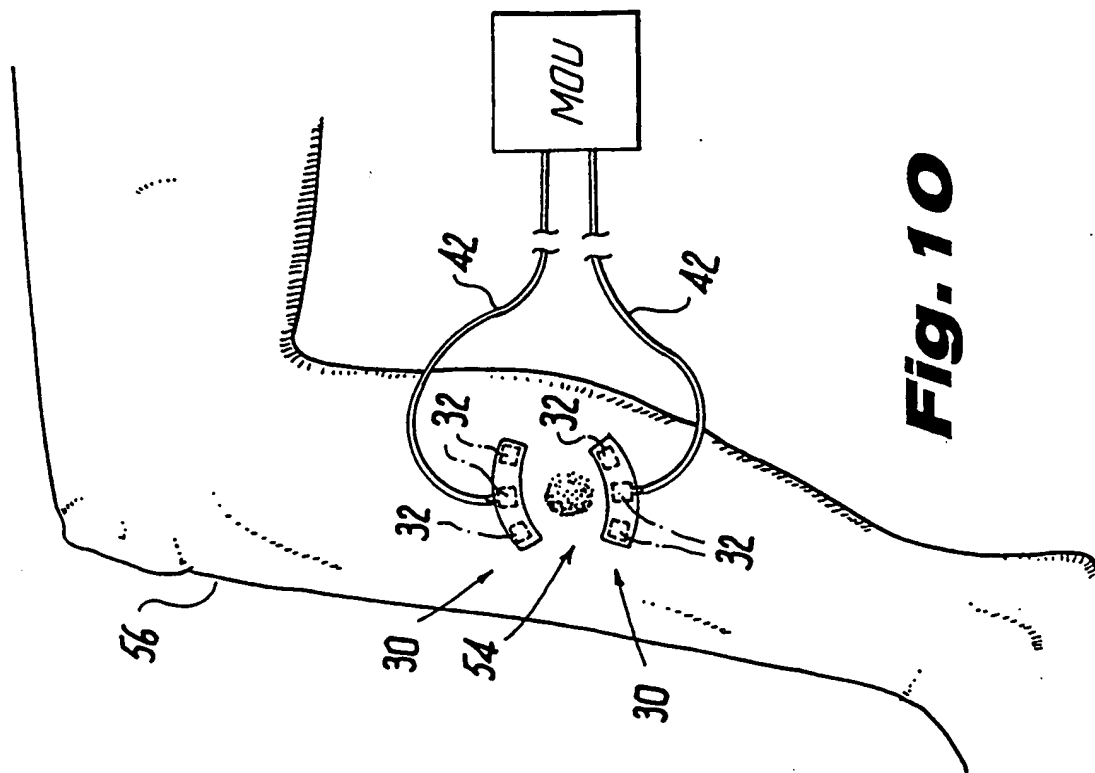


Fig. 10

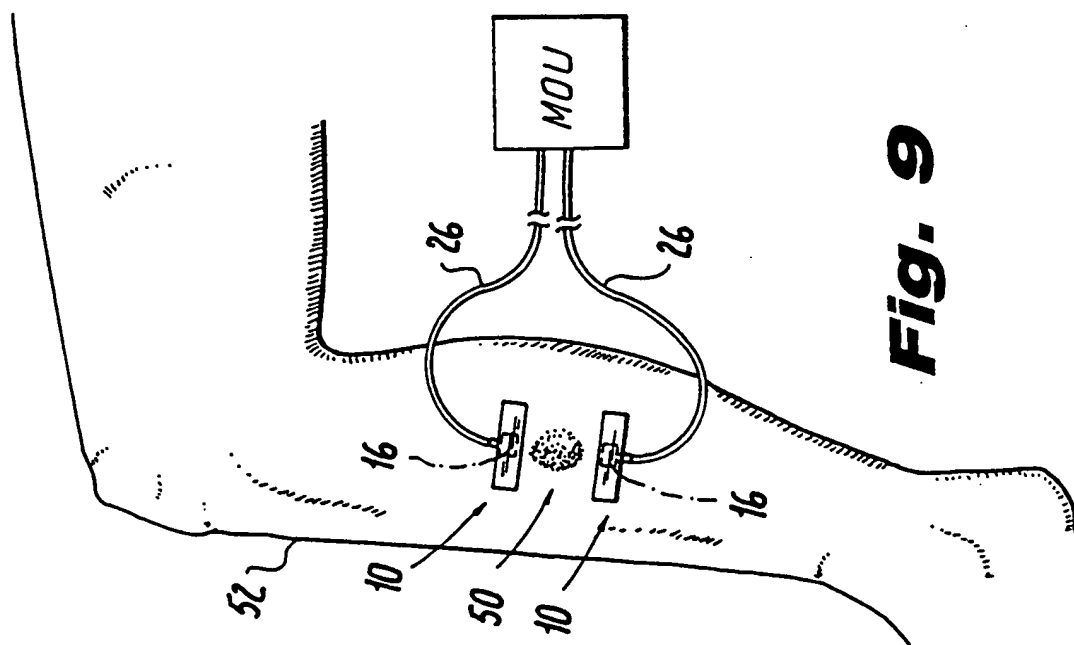


Fig. 9

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 99/09875

A. CLASSIFICATION OF SUBJECT MATTER

IPC 6 A61N7/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61N G10K A61H A61M B06B A61F A61L

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 4 787 888 A (FOX MARTIN D) 29 November 1988 (1988-11-29) cited in the application	1-3, 22-24, 41-43, 62-64
A	column 3, line 63 - column 4, line 4; figure 1	6, 20, 27, 40, 46, 60, 66, 81
Y	EP 0 181 506 A (EDO WESTERN CORP) 21 May 1986 (1986-05-21)	1-3, 22-24, 41-43, 62-64
A	page 6, line 7 - line 13; figure 1	6, 20, 27
A	page 7, line 3 - line 8	40, 46, 60, 81

X Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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Date of the actual completion of the international search

28 July 1999

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PCT/US 99/09875

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 4 933 230 A (CARD ROGER J ET AL) 12 June 1990 (1990-06-12)	4-9, 25-29
A	column 4, line 29 - line 43	44-49
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A	column 7, line 9 - line 26; figure 3	31,36
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A	column 4, line 30 - line 35; figure 2	38,43, 57,58, 64,78,79

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 99/ 09875

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 82-87
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy
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Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

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Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

National Application No

PCT/US 99/09875

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US

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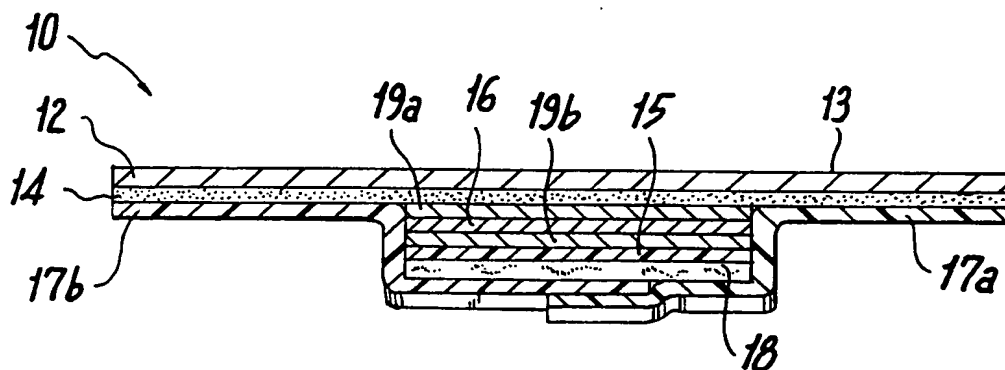
(74) Agents: CARTER, David, M. et al.; Dilworth & Barrese, 333 Earle Ovington Boulevard, Uniondale, NY 11553 (US).

(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published

With international search report.

(54) Title: ULTRASOUND BANDAGES



(57) Abstract

Ultrasound bandages (10) and ultrasound transducer array bandages are provided herein to accelerate the healing of wounds by positioning the ultrasound bandages (10) and ultrasound transducer array bandages adjacent to a wound and generating ultrasonic pulses. The ultrasound bandages (10) generally include (a) a backing layer (12), (b) an adhesive layer (14) applied to, and substantially coextensive with, the backing layer (12), and (c) a transducer material (16) disposed on at least a portion of the adhesive layer (14). The ultrasound transducer array bandages generally include (a) a backing layer (13), (b) an adhesive layer applied to, and substantially coextensive with, the backing layer (13), and (c) an array comprising a plurality of transducer materials arranged in adjacent relation to define spaces therebetween, the array being disposed on at least a portion of the adhesive layer. The resulting ultrasound bandages (10) and ultrasound transducer array bandages allows for medical therapeutic applications as promoting the healing of wounds such as abrasions, lacerations, incisions and ulcers at any section or multiple sections of the human anatomy with the ultrasound bandages (10) and ultrasound transducer array bandages being conveniently discarded after each application and a new bandage then being applied for the next application.

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